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(11) EP 1 055 398 A1

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# **EUROPEAN PATENT APPLICATION**

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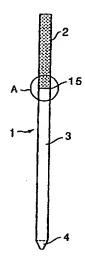
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### (54) BONE FIXING PIN

(57) A bone fixing pin comprising a pin body section (2) made of poly-L-lactic acid and a metal drilling section (3) joined to the pin body section (2) and having at the free end a drill (4), wherein at least the pin body section (2), preferably both the body section (2) and the drilling section (3) are formed in a columnar shape having the same diameter along the entire lengths thereof, whereby the pin can be pushed into (embedded in) a bone piece to be fixed simply and smoothly without any loosening after the embedding. The embedded pin body section (2) made of poly-L-lactic acid is absorbed and vanishes in the organism after synotosis.

# FIG. 1



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#### Description

#### Technical field

[0001] This invention relates to a bone fixing pin which is for use in fixation in osteosynthese, fixation after osteotomy, fixation of a transplantation bone, arthrodesis, complement, or supporting in an orthopedical and the like areas. The invention relates more concretely to a bone fixing pin which is for use in restoration of fracture portions, such as fixation of fractures of a distal end of humerus, a proximal end of humerus, a distal end of forearm bone, clavicule, bone's of digits, and the like, fixation after osteotomy in hallux valgus, rotational acetabular osteotomy, high tibial osteotomy, and the like, fixation of a bone graft (ilium, etc.), arthrodesis in polyarthritis rheumatica chronica, arthrodesis in osteoarthritis deformans, and the like, supporting in fracture of a remote end of the radius, and complement or supporting in therapy of osteoporosis.

#### Background technique

**[0002]** When fixation in osteosynthese, fixation after osteotomy, fixation of a transplantation bone. arthrodesis, and so on are carried out in an orthopedical and the like areas, generally employed are methods in which fixation is completed by the use of a metallic implant, such as a screw, a plate, a pin, and a wire, after provisionally fixing a plurality of bone fragments by inserting a metallic pin and a metallic wire into the bone fragments to be thereby supported. In these methods, when the metallic pin is used as an implant, the metallic pin must be extracted therefrom by carrying out an extracting operation after bane assimilation. Due to a readmission to a hospital and a re-operation for extracting the pin, there are problems that QOL (Quality of Life) is reduced and that increase of medical treatment cost is caused. Further, there is a danger of re-fracture, when the pin is extracted therefrom.

[0003] Accordingly, a pin which is not required to be extracted after bone assimilation has been used by using such a bio-absorptive polymer as divided gradually in an organism and eliminated after a certain period has passed as a material of a pin. Namely, in order to use this pin, at first, a metallic pin, such as a kirschner steel wire, of which a head is processed to be able to cut a bone is driven into a desirable position, so that hone fragments are provisionally fixed to each other. Next, a perforation is made at the other position by the use of a drill, and a bone fixing pin consisting of the bio-absorptive polymer is pushed into the perforation.

[0004] However, in a case of using such a pin, a perforation which does not attribute to junction of the bone fragments to each other must be made, when the metallic pin for provisional fixation, such as a kirschner steel wire, is driven thereinto. Further, on a practical use, the metallic pin for provisional fixation is often

driven into a position which is the most desirable for restoration and fixation of the bone fragments. This causes a problem that the main bone fixing pin consisting of bio-absorptive polymer is inevitably driven into a next desirable position other than the most desirable position.

[0005] Under these circumustances, a proposal is made about a bone fixing pin which is consisting of the bio-absorptive polymer and which can be driven into the most desirable position for the fixation of the bone fragments to each other, since it is not required to fix the bane fragments provisionally to each other by the use of a metallic pin therebefore. Further, in the proposal, a perforation can be made into a bone by this bone fixing pin itself without independently using a drill (See an official gazette of unexamined Japanese Patent Publication Hei 2-63450).

[0006] Namely, the bone fixing pin disclosed in the official gazette of unexamined Japanese Patent Publication Hei 2-63450 has a constitution in which a perforating section having a drill is joined to a cylindrical pin body section made from polymeric material. Further, the perforating section having the drill is formed to have a cylindrical shape. On the other hand, the pin body section is formed to have a taper enlarging the diameter thereof toward the direction opposite to that the pin body section is pushed thereinto. Besides, poly-dioxanone is disclosed in the official gazette as a preferable absorptive polymer.

[0007] However, in the bone fixing pin disclosed in the above-mentioned official gazette, the pin body section has the taper, so that loose of the pin body section is readily caused to occur within a perforation which is made by the perforating section having the drill. Further, since the pin body section has the taper, strength never become uniform over the whole of the pin body section, in other words, over the whole of a bone-joined portion. In addition, since the bone fixing pin has the taper enlarging the diameter thereof toward the direction opposite to that the pin body section is pushed thereinto, a considerably large strength must be added to make the pin body section be pushed thereinto. A special instrument for the purpose thereof must be prepared. Furthermore, as the poly-dioxanone used as a material for the pin body section has a comparatively small strength, the poly-dioxanone cannot be resistant to a large load. Moreover, the poly-dioxanone is divided comparatively fast in an organism. Accordingly, this bone fixing pin has a problem that applicable portions are restricted to bone's of digits or the like.

[0008] The present invention solves the aforesaid problems of the conventional bone fixing pin. It is therefore an object of the present invention to provide a bone fixing pin, which is not required to be extracted therefrom even after bone assimilation, which can readily and smoothly be pushed into the most desirable position for fixation of the bone fragments to each other with the bone fixing pin making a perforation into the bone by

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itself, in which loose of the bone fixing pin is never caused to occur within the perforation thereby made, and for which applicable portions are increased.

[0009] It is yet another object of the present invention to provide use of a bone fixing pin, that is a therapy of osteoporosis.

[0010] It is further object of the present invention to provide a bone fixing pin to which roentgenography can be applied.

Disclosure of the Invention:

[0011] In order to achieve the above objects, a bone fixing pin of the present invention comprises a pin body section consisting of bio-absorptive high polymer, a perforating section which is joined to said pin body section and which has a drill at a head thereof, and is characterized in that at least said pin body section is formed to have the same thickness through the whole of the length direction thereof.

[0012] Namely, according to an aspect of the present invention, there is provided a bone fixing pin comprising: a pin body section consisting of bio-absorptive high polymer; a perforating section which is joined to said pin body section and which has a drill at a head thereof; characterized in that at least said pin body section is formed to have the same thickness through the whole of the length direction thereof.

[0013] Preferably, said perforating section is formed to have a cylindrical shape having a drill at a head thereof, and said pin body section is formed to have a cylindrical shape having the same diameter through the whole of the length direction thereof.

[0014] Further desirably, substantially whole of said bone fixing pin consisting of both said perforating section except for said drill at a head thereof and said pin body section is formed to have a cylindrical shape having the same diameter through the length direction thereof.

[0015] Herein, the bio-absorptive high polymer constituting said pin body section means a high polymeric material that is used as an implant material for operation and that is gradually absorbed in an organism and naturally eliminated after the operation.

[0016] Listed hereinunder can be used as the bioabsorptive high polymer.

[0017] At first, the following can be listed as synthetic high polymer.

polyester; poly-glycollic acid, poly-lactic acid, poly-lactic acid, poly-D-lactic acid, poly-D, L-lactic acid, poly-caprolacton, poly-dioxanone, poly-lacton, poly-( $\alpha$ -malic acid)) poly-( $\beta$ -malic acid), poly-( $\alpha$ -malic acid), etc.

polyamino acid; poly-glutamic acid, poly-aspartic 55 acid, etc.

polycarbonate; poly-trimethylene carbonate, etc. poly-( $\alpha$  -cyanoacrylate), poly-( $\alpha$  -cyanoacrylate),

etc.

anhydride; poly-anhydride, etc. ortho ester; poly-ortho ester, etc. having nitrogen-phosphorus bond; poly-phosphazen, etc.

[0018] Further, the following can be listed as natural . high polymer.

polyester; poly-hydroxybutyric acid, poly. hydroxyvaleric acid, etc. polypeptide; gelatin, collagen, etc. polyphosphate; polyglycoside; starch, chitin, etc.

[0019] The above-listed high polymer or copolymer combining the above-listed high polymers together can be used as the bio-absorptive high polymeric material constituting the pin body section.

[0020] Further, composites having a high bio-affinity, such as hydroxyapatite, calcium phosphate, calcium hydrogenphosphate, calcium carbonate, calcium hydrogencarbonate, or the like may be added to said bioabsorptive high polymeric material as an additive. Accordingly, bio-affinity of the bone fixing pin can be improved. Further, hydroxyapatite, calcium phosphate, calcium hydrogenphosphate, calcium carbonate, calcium hydrogencarbonate, or the like is more hard to be transmitted by X-ray, compared with the bio-absorptive high polymer. By adding these, X-ray transmittance of the bio-absorptive high polymer can be reduced. It becomes easy to confirm a position, a condition of disappearance, and the like of the bone fixing pin by roentgenography after operation. Hydroxyapatite and calcium phosphate are preferable as an additive.

[0021] Preferably, the following can be listed as the bio-absorptive high polymer.

[0022] Namely, the following can be listed as synthetic high polymer.

polyester; poly-glycollic acid, poly-lactic acid, poly-L-lactic acid, poly-D-lactic acid, poly-D, L-lactic acid, poly-caprolacton, poly-dioxanone, poly-lacton, poly-(  $\alpha$ -malic acid), poly-(  $\beta$ -malic acid), poly-(  $\alpha$ ,  $\beta$ -malic acid), etc.

polyamino acid; poly-glutamic acid, poly-aspartic acid, etc.

polycarbonate; poly-trimethylene carbonate, etc. poly-(  $\alpha$  -cyanoacrylate); poly-(  $\alpha$  -cyanoacrylate), etc.

anhydride; poly-anhydride, etc. ortho ester; poly-ortho ester, etc.

having nitrogen-phosphorus bond; poly-phosphazen, etc.

[0023] Further, the following can be listed as natural high polymer.

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polyester; poly-hydroxybutyric acid, poly-hydroxy-valeric acid, etc.

polyphosphate; polyglycoside; chitin, etc.

[0024] As a copolymer, a copolymer combining mainly polyester(for example, poly-glycollic acid, poly-lactic acid, poly-L-lactic acid, poly-caprolacton, poly-dioxanone) and subordinately the other, a copolymer including poly-L-lactic acid, a stereocomplex blending poly-L-lactic acid and poly-D-lactic acid, and the like are preferable.

[0025] Further, poly-L-lactic acid including hydroxyapatite, poly-L-lactic acid including calcium phosphate, a copolymer including poly-L-lactic acid, a stereocomplex blending poly-L-lactic acid and poly-D-lactic acid, and the like are also preferable.

[0026] In particular, poly-L-lactic acid, a copolymer including poly-L-lactic acid, a stereocomplex blending poly-L-lactic acid and poly-D-lactic acid, poly-L-lactic acid including hydroxyapatite are preferable.

[0027] Moreover, as a method of joining said pin body section and said perforating section, for example, a talking method, a screwing method, a hooking method, a blinding method, and the like can be listed. Among them, calking method is desirable in respect of strength. Further, also in a method other than the calking method, in order to reinforce the joined portion, there is an another method in which the joined portion is fixed by pressurizing therearound, after portions to be joined of said pin body section and said perforating section are interfit to each other.

[0028] In particular, in a case that poly-L-lactic acid or a copolymer including poly-L-lactic acid is used as a material of said pin body section, since the poly-L-lactic acid, and so on have a certain strength, the portion joined to the perforating section is easily worked. Thus, in the case, the method in which the joined portion is fixed by pressurizing therearound after portions to be joined of said pin body section and said perforating section are interfit to each other can be readily carried out. By employing these methods of joining, it is not necessary to use an adhesive for joining the pin body section and the perforating section to each other. Accordingly, it is not dangerous that components of the adhesive remain in an organism, so that the bone fixing pin of the present invention can be safely used.

Brief Description of the Drawings:

#### [0030]

Fig. 1 is a view for showing the whole constitution of a bone fixing pin according to a preferred embodiment of the present invention;

Fig. 2 is a cross sectional view for showing an enlarged portion A of the bone fixing pin illustrated in Fig. 1;

Fig. 3 is a cross sectional view similar to Fig. 2 for showing the portion A of a bone fixing pin according to another embodiment of the present invention;

Fig. 4 is a cross sectional view similar to Fig. 2 for showing the portion A of a bone fixing pin according to still another embodiment of the present invention:

Fig. 5 is a view for explaining a screwing method as a method of joining the pin body section and the perforating section;

Fig. 6 is a view for explaining a hooking method as a method of joining the pin body section and the perforating section;

Fig. 7 is a view for explaining a blinding method as a method of joining the pin body section and the perforating section, and is also a cross sectional view showing a condition before the joining;

Fig. 8 is a view for explaining a blinding method as a method of joining the pin body section and the perforating section, and is also a cross sectional view showing a condition in which the pin body section and the perforating section have been joined to each other;

Fig. 9 is a view for explaining the method of using the bone fixing pin illustrated in Fig. 1, and is also a view showing a condition in which a part of the pin body section is buried into the perforation; and Fig. 10 is a view for explaining the method of using the bone fixing pin illustrated in Fig. 1, and is also a

the bone fixing pin illustrated in Fig. 1, and is also a view showing a condition in which substantially whole of the pin body section is completely buried into the perforation.

The best mode for putting the invention into practice:

[0031] In order to describe the present invention more in detail, the description will be made in accordance with the drawings.

[0032] At first, referring to Figs. 1, 2, 9 and 10, description is made about a bone fixing pin according to a first embodiment of the present invention. Fig. 1 is a view for showing the whole constitution of a bone fixing pin according to an embodiment of the present invention while Fig. 2 is an enlarged cross-sectional view for showing a portion A in Fig. 1. Figs. 9 and 10 are views for explaining the method of using the bone fixing pin according to an embodiment of the present invention.

[0033] As illustrated in Fig. 1, a bone fixing pin 1 according to an embodiment of the present invention comprises a pin body section 2 and a perforating section 3.

[0034] The pin body section 2 is made from poly-Llactic acid which is a bio-absorptive material and of which strength is comparatively high. Further, the pin body section 2 is formed to have a cylindrical shape having the same diameter through the whole of the length direction thereof. Herein, the diameter and the total length of the cylindrical pin body section 2 may be

appropriately selected, dependent on a portion to which the bone fixing pin 1 of the present invention is applied. For example, when small size bone fragments, such as facial inferior floor, bone's of digits, a genual bone, or the like are to be fixed, it is preferable that the cylindrical pin 5 body section 2 has a diameter of 0.6 through 2.0 mm and a total length of 10 through 50 mm. When medium size bone fragments of a brachial portion, an antebrachial portion, an ankle region, ilium for implantation, or the like are to be fixed, it is preferable that the cylindrical pin body section 2 has a diameter of 1.0 through 4.0 mm and a total length of 10 through 100 mm. When large size bone fragments of shoulder hones, clavicle, femur, tibia, fibula, or the like are to be fixed, it is preferable that the cylindrical pin body section 2 has a diameter of 2.0 through 20 mm and a total length of 10 through 500 mm.

[0035] Besides, since the cylindrical pin body section 2 is made from poly-L-lactic acid which is a bio-absorptive high polymeric material as described above, the bone fixing pin 1 is more flexible than that having a metallic pin body section. Further, the bone fixing pin 1 would lose the strength thereof gradually in an organism, after having fixed the bone once. The bone fixing pin 1 can therefore be applied to children of which bones are growing.

[0036] The perforating section 3 is made of a metal and has a drill portion 4 in a head side thereof. Further, the perforating section 3 is made to have a cylindrical shape including a total length of 150 mm and the same diameter as that of the pin body section 2 except for the drill portion 4. Besides, the diameter of the perforating section 3, similarly to the diameter of the pin body section 2, may be appropriately selected within a range between 0.6 mm and 20 mm, dependent on a portion to which the bone fixing pin 1 is applied. Thus, in this embodiment, the diameter of the perforating section 3 through the length direction thereof except for the drill portion 4 is determined to be the same as that of the pin body section 2. Accordingly, as will later be described. once the perforating section 3 has been joined to the pin body section 2, whole of the bone fixing pin 1 except for the drill portion 4 is constituted to have a cylindrical shape having the same diameter through the length direction thereof.

[0037] The perforating section 3 is to be joined to the pin body section 2. In this embodiment, as a method of joining, what is called, press-calking method is employed. In the press-calking method, as illustrated in Fig. 2, a convex portion formed in one end of the pin body section 2 is interfit into a recessed portion formed at the end of the opposite side of the perforating section 3 to that of the drill portion 4, and the interfit portion is then calked by pressing from the both sides thereof.

[0038] Besides, dependent on extent to which the interfit portion is thus pressed from the both sides, a structure in which a stage is defined in the joined portion by such a calking may be alternatively employed, as illustrated in Fig. 3.

[0039] Further, a shape of the joined portion is not restricted to those mentioned above. For example, as illustrated in Fig. 4, an alternative structure may be considered. In the alternative structure, the convex portion formed in one end of the pin body section 2 may be formed to have a two-stage structure consisting of a large diameter portion in the head side thereof and a small diameter portion in the root side thereof. With the structure, after the calking, a metal of the perforating section 3 is passed around the small diameter portion to improve the joining strength.

[0040] As methods for joining the pin body section 2 with the perforating section 3, the followings can further be considered.

[0041] In Fig. 5, illustrated is a screwing method, in which a female screw 3a is carved in the one side while a bolt 2a is formed in the other side, and in which the bolt 2a is tightened with the female screw 3a. In Fig. 6, illustrated is a hooking method, in which an inserting portion 2b having a protrusion 2b ' in perpendicular to the head thereof is formed in the one side. On the other hand, an insertable hole 3b into which the inserting portion 2b is inserted is formed in the other side. Further, a recessed portion 3b ', in which the protrusion 2b ' is inserted to be hooked therein, is formed in the inner part of the insertable hole 3b. Accordingly, by inserting the inserting portion 2b into the insertable hole 3b and twisting the inserting portion 2b therein, the protrusion 2b 'is hooked in the recessed portion 3b '. In Figs. 7 and 8. illustrated is a bamboo blind method, in which, at the end portion of the one side, a plurality of protruding pieces 3c, 3c are formed in the axial direction thereof with being arranged in a bamboo blind fashion. In addition, protrusions 3c', 3c'each of which is protruding to the inside are formed at the heads of these protruding pieces 3c, 3c, respectively. On the other hand, a recessed portion 2c in which the protruding pieces 3c and the protrusions 3c ' are inserted is formed on the outer circumferential surface of the other side. In this case, the protruding pieces 3c are slided into the recessed portion 2c, and the protrusions 3c ' are then hooked into an one-stage deeper portion 2c ' of the recessed portion 2c.

[0042] Next, also referring to Figs. 9 and 10, description is made as regards a method of using the bone fixing pin 1 according to this embodiment.

[0043] Figs. 9 and 10 are views for explaining the method of using the bone fixing pin 1. Fig. 9 shows a condition in which the bone fixing pin 1 has perforated osseous tissue and a part of the pin body section 2 is buried into a perforation. Fig. 10 further shows a condition in which whole of the pin body section 2 is completely buried into the perforation. Besides, in the figures, 5 shows a bone, 5A and 5B show fractured both bone fragments in a bone 5, and 6 shows a perforation perforated through the both bone fragments 5A and 5B by the drill portion 4.

[0044] In the interim, in order to fix bone fragments

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to each other by the bone fixing pin 1, upon adjusting the bone fragments 5A and 5B as they used to be, at first, a perforation is made in the best position for fixing the bone fragments 5A to 5B by the use of the drill portion 4. With the perforation being made, the perforating portion 3 is buried into a perforation 6 digged by the drill portion 4 through the both bone fragments 5A and 5B, as illustrated in Fig. 9. Further, as illustrated in the figure, when the perforating portion 3 has penetrated from the inward of the perforation 6 down to the opposite side of the bone 5 (In the figure, the lower side of the bone fragment 5B), the perforating portion 3 is gripped by an unillustrated appropriate instrument, such as a hammer having a chuck, or the like so as to be pulled out of the opposite side. Alternatively, the perforating portion 3 is pushed from the upper side of the pin body section 2 by a pinpusher and so on, when the perforating portion 3 has thus penetrated. Accordingly, a condition that a part of the pin body section 2 is exposed from the opposite side of the bone 5 (In the figure, the lower side of the bone fragment 5B) has been achieved, as illustrated in Fig. 10. Thus, according to the bone fixing pin 1 of this embodiment, the perforation 6 in which the pin body section 2 is buried can be made by the use of the drill portion 4 integrated with the perforating portion 3. From the first, the bone fixing pin 1 can be inserted into the best position for fixing bone. Furthermore, according to the bone fixing pin 1 of this embodiment, substantially whole of the bone fixing pin 1 including both the perforating section 3 and the pin body section 2 except for the drill portion 4 is formed to have a cylindrical shape having the same diameter through the length direction thereof. The bone fixing pin 1 can therefore be pushed into (buried into) such the best position for fixing bones readily and smoothly, different from a conventional bone fixing pin, and the like, of which a pin body section is provided with a taper.

Besides, when the perforating portion 3 is gripped to be pulled out, it is sometimes caused to occur that a considerable part of the pin body section 2 is exposed from the opposite side of the bone 5 (In the figure, the lower side of the bone fragment 5B) due to the over pull of the perforating portion 3. Consequently, a length of a remaining part of the pin body section 2 within the bone 5 is not enough to fix the bone fragments 5A and 5B. In such a case, alternatively, the perforating portion 3 may be pushed from the opposite side of the bone 5 (In the figure, the lower side of the bone fragment 5B) to be returned into the perforation 6. In this case, according to the bone fixing pin 1 of this embodiment, since substantially whole of the bone fixing pin 1 including both the perforating section 3 and the pin body section 2 except for the drill portion 4 is formed to have a cylindrical shape having the same diameter through the length direction thereof, a length of a buried part of the pin body section 2 (a position of the pin body section 2 in depth) within the bone 5 can readily be adjusted.

Thereafter, the pin body section 2 is cut at

the position projecting from the perforation 6 by the use of an unillustrated appropriate instrument, such as a cutting nipper, a scalpel, or the like, as illustrated in Fig. 10. Besides, C in the figure shows the cutting portion. Accordingly, only the pin body section 2 remains buried within the bone 5, so that the pin body section 2 fixes the bone fragments 5A and 5B. According to the bone fixing pin 1 of this embodiment, at least the pin body section 2 is formed to have a cylindrical shape having the same diameter through the length direction thereof. Loose of the pin body section 2 is never caused to occur within the perforation 6, different from a conventional bone fixing pin, and the like, of which a pin body section is provided with a taper. Further, since strength of the pin body section 2 is uniform over the whole of the pin body section 2, a joined portion of the bone can be fixed to be well-balanced at the uniform strength.

[0047] Thereafter, the pin body section 2 is made from poly-L-lactic acid that is the bio-absorptive high polymeric material, the pin body section 2 is gradually absorbed in an organism and naturally eliminated. Therefore, it is not necessary to extract the pin body section 2 from the buried portion by carrying out an extracting operation after bone assimilation. Consequently, it is not caused to occur that QOL is reduced and that medical treatment cost is increased, due to a re-admission to a hospital and a re-operation for extracting the pin body section 2. Further, there is no danger of re-fracture, when the pin is extracted therefrom.

[0048] Besides, strength of poly-L-lactic acid used as a material of the pin body section 2 in the bone fixing pin 1 according to this embodiment is larger than that of poly-dioxanone used as a material of a pin body section in the conventional example. As a result, the poly-L-lactic acid used as the material of the pin body section 2 can be resistant to a comparatively large load. Accordingly, the bone fixing pin 1 can be applied to various portions.

As described above, although the present invention is described in conjunction with the specific embodiment thereof, the present invention is not restricted to the embodiment mentioned above. The present invention can be applied to various other embodiments within the scope described in the claims. [0050] For example, in the above-mentioned embodiment, description was made as regards an example in which substantially whole of the bone fixing pin including both the perforating section and the pin body section except for the drill portion is formed to have a cylindrical shape having the same diameter through the length direction thereof However, it is enough that at least the pin body section is formed to have the same thickness through the length direction thereof With the structure thus mentioned, the bone fixing pin can be pushed into (buried into) bones readily and smoothly, compared with a conventional bone fixing pin of which a pin body section is provided with a taper. In addition, loose of the bone fixing pin is never caused

[0049]

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to occur even after the bone fixing pin has been buried into the bones.

[0051] Therefore, any portions other than the pin body section (the perforating section or a joined portion between the pin body section and the perforating section as well as the drill portion, of course) are not required to have the same diameter, and the like as the pin body section. Further, whole of the bone fixing pin including the pin body section is not required to have a cylindrical shape. For example, another shape having an elliptical or a rectangular cross section, etc.. may be alternative. However, the cylindrical shape (having the circular cross section) is preferable on a practical use.

#### Possibility of industrial use:

[0052] The present invention has a constitution thus mentioned above, that is a bone fixing pin, in which the pin body section buried into a bone is consisting of the bio-absorptive high polymer, and in which the pin body section can be inserted into the best position for fixing the bone fragments to each other at the same time when the bone fixing pin penetrates the bone. By forming whole of the pin body section to have the same thickness through the length direction thereof, it has become possible that the whole of the pin body section is completely fitted into a perforation made by a drill. Therefore, loose of the pin body section is never caused to occur within the perforation. In addition, since strength of the pin body section is uniform over the whole of the pin body section, a joined portion of the bone fragments to each other can be fixed to be wellbalanced at the uniform strength. Particularly, poly-Llactic acid has a large strength. Therefore, strength of the pin body section is further improved, in a case that the bio-absorptive high polymer is poly-L-lactic acid. Further, the bone fixing pin can smoothly be pushed into the perforation. Any specific instrument is not required for pushing the bone fixing pin into the perforation. In order to enable the bone fixing pin to be used for fixing a large size, a medium size, and a small size bones, it is possible that the bone fixing pin having a size suitable for each of them is provided. Moreover, the pin body section is made from a bio-absorptive material, it is not necessary to carry out an extracting operation after bone assimilation.

[0053] In the interim, now pharmacotherapy or the like are carried out as a therapy of osteoporosis. It is also useful to use the bone fixing pin of the present invention for the purpose of reinforcing the bone of the osteoporosis. Namely, osteoporosis is defined as, for example "A condition in which bone mass is decreased to cause a large danger of fragility fracture", and employed is a therapy for restoring the bone mass in which bone resorption is controlled by estrogen, calcium, calcitonin, activated vitamin D, and the like, and in which osteogenesis is promoted by parathyroid hormone, vitamin K<sub>2</sub>, androgen, and the like. By inserting

the bone fixing pin of the present invention into a bone in which bone mass is decreased and bone density becomes small for use in supporting or complement of the bone, it is possible to wait the restoration of bone mass by the pharmacotherapy, or the like, with a danger of fracture being avoided. Besides, in a case that the bone fixing pin of the present invention is used for such a therapy of osteoporosis, it is preferable that the pin body section is consisting mainly of bio-absorptive high polymer and that hydroxyapatite, calcium phosphate, calcium hydrogenphosphate, calcium carbonate, calcium hydrogencarbonate, or the like is added to the bioabsorptive high polymer as an additive. Accordingly, it becomes easy to confirm a position, and the like of the bone fixing pin by roentgenography after the insertion. Further, the bone fixing pin can be eliminated by the time when bone mass is restored by the pharmacotherapy, or the like

#### ∾ Claims

#### 1. A bone fixing pin comprising:

a pin body section consisting of bio-absorptive high polymer; and

a perforating section which is joined to said pin body section and which has a drill at a head thereof:

characterized in that at least said pin body section is formed to have the same thickness through the whole of the length direction thereof.

- 2. A bone fixing pin as claimed in claim 1, characterized in that said perforating section is formed to have a cylindrical shape having a drill at a head thereof, and that said pin body section is formed to have a cylindrical shape having the same diameter through the whole of the length direction thereof.
  - 3. A bone fixing pin as claimed in claim 1, characterized in that substantially whole of said bone fixing pin consisting of both said perforating section except for said drill at a head thereof and said pin body section is formed to have the same thickness through the length direction thereof.
  - 4. A bone fixing pin as claimed in claim 2, characterized in that substantially whole of said bone fixing pin consisting of both said perforating section except for said drill at a head thereof and said pin body section is formed to have a cylindrical shape having the same diameter through the length direction thereof.
  - A bone fixing pin as claimed in claims 1 through 4, characterized in that said bio-absorptive high polymer is poly-L-lactic acid or copolymer including

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poly-L-lactic acid.

- 6. A bone fixing pin as claimed in claims 1 through 5, characterized in that at least one of hydroxyapatite, calcium phosphate, calcium hydrogenphosphate, salcium carbonate, calcium hydrogencarbonate is added to said bio-absorptive high polymer as an additive.
- A bone fixing pin as claimed in claims 1 through 6, characterized in that said pin body section and said perforating section are joined to each other by either calking method, screwing method, hooking method or blinding method.
- 8. A bone fixing pin as claimed in claims 1 through 7 characterized in that the joined portion of said pin body section and said perforating section has the same thickness as those of the other portions of said pin body section and said perforating section.
- 9. A bone fixing pin as claimed in claims 1 through 7, characterized in that the joined portion of said pin body section and said perforating section is thinner than the other portions of said pin body section and said perforating section, and that a recessed portion is formed in said joined portion.
- 10. A bone fixing pin comprising:

 a pin body section consisting of poly-L-lactic acid or copolymer including poly-L-lactic acid;
 and

a perforating section which is joined to said pin body section and which has a drill at a head thereof.

- 11. A bone fixing pin for use in a therapy of osteoporosis, comprising:
  - a pin body section consisting of bio-absorptive high polymer; and
  - a perforating section which is joined to said pin body section and which has a drill at a head thereof;
  - characterized in that said bone fixing pin is used in supporting or complement of bone for therapy of osteoporosis.
- 12. A bone fixing pin for use in a therapy of osteoporosis as claimed in claims 11, characterized in that at least said pin body section is formed to have the same thickness through the whole of the length direction thereof.
- 13. A bone fixing pin for use in a therapy of osteoporosis as claimed in claims 12, characterized in that said perforating section is formed to have a cylindri-

cal shape having a drill at a head thereof, and that said pin body section is formed to have a cylindrical shape having the same diameter through the whole of the length direction thereof.

- 14. A bone fixing pin for use in a therapy of osteoporosis as claimed in claims 13, characterized in that substantially whole of said bone fixing pin consisting of both said perforating section except for said drill at a head thereof and said pin body section is formed to have the same thickness through the length direction thereof.
- 15. A bone fixing pin for use in a therapy of osteoporosis as claimed in claims 14, characterized in that substantially whole of said bone fixing pin consisting of both said perforating section except for said drill at a head thereof and said pin body section is formed to have a cylindrical shape having the same diameter through the length direction thereof.
- 16. A bone fixing pin for use in a therapy of osteoporosis as claimed in claims 11 through 15, characterized in that said bio-absorptive high polymer is poly-L-lactic acid or copolymer including poly-L-lactic acid.
- 17. A bone fixing pin for use in a therapy of osteoporosis as claimed in claims 11 through 16, characterized in that at least one of hydroxyapatite, calcium phosphate, calcium hydrogenphosphate, calcium carbonate, calcium hydrogencarbonate is added to said bio-absorptive high polymer as an additive.
- 18. A bone fixing pin comprising:

a pin body section; and

a perforating section which is joined to said pin body section and which has a drill at a head thereof;

characterized in that an image of said bone fixing pin is capable of being picked up by X-ray.

19. A bone fixing pin of which an image is capable of being picked up by X-ray as claimed in claim 18, characterized in that said pin body section is consisting mainly of bio-absorptive high polymer, and that at least one of hydroxyapatite, calcium phosphate, calcium hydrogenphosphate, calcium carbonate, calcium hydrogencarbonate is added to said bio-absorptive high polymer as an additive.

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FIG. 1

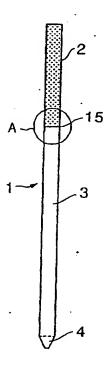


FIG. 2

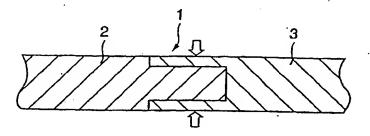


FIG. 3

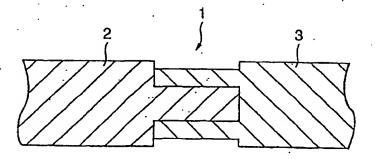


FIG. 4

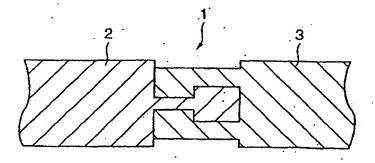


FIG. 5

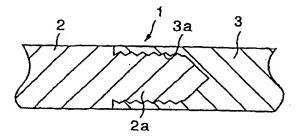


FIG. 6

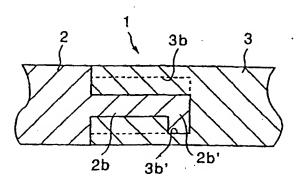


FIG. 7

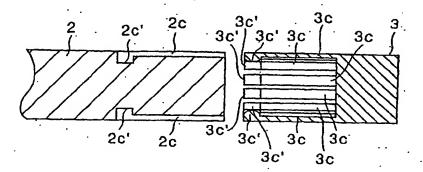


FIG. 8

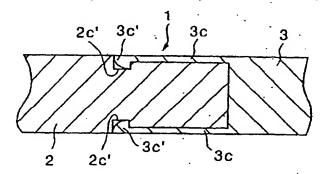


FIG. 9

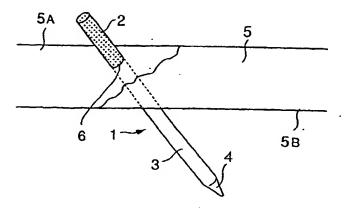
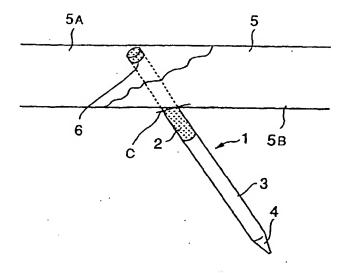


FIG. 10



# EP 1 055 398 A1

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP99/00585

A. CLASSIFICATION OF SUBJECT MATTER			
Int.Cl A61B17/58			
According to International Patent Classification (IPC) or to both national classification and IPC			
B. FIELDS SEARCHED			
Minimum documentation searched (classification system followed by classification symbols)  Int.C1 A61B17/58			
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Jitsuyo Shinan Koho 1940-1996 Toroku Jitsuyo Shinan Koho 1994-1999 Kokai Jitsuyo Shinan Koho 1971-1995 Jitsuyo Shinan Toroku Koho 1996-1999			
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)			
C. DOCUMENTS CONSIDERED TO BE RELEVANT			
Category*			Relevant to claim No.
Y .	JP, 2-63450, A2 (Johnson & Johnson Orthopaedics, 1-19 Inc.), 2 March, 1990 (02. 03. 90) & US, 4858603, A & EP, 346033, A1 & US, 4944742, A		
<b>Y</b> .	JP, 63-68155, A2 (Gunze Ltd.), 28 March, 1988 (28. 03. 88) £ WO, 88/1849, A1		1-19
¥	JP, 3-29663, A2 (Takiron Co. 7 February, 1991 (07. 02. 91		1-19
Further documents are listed in the continuation of Box C.  See patent family annex.  * Special categories of cited documents:  The document defining the general state of the art which is not considered to be of particular relevance.  The document defining the general state of the art which is not considered to be of particular relevance.  The document of particular relevance, the claimed invention cannot be document of particular relevance; the claimed invention cannot be			tion but cited to understand rention
"L' document which may throw doubts on priority chaim(i) or which is cited to exablish the publication date of another citation or other special reason (as specified)  "O" document referring to an oral disclosure, use, exhibition or other			ed to involve se inventive step
means  "P" document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family			
Date of the actual completion of the international search 23 April, 1999 (23. 04. 99)  Date of mailing of the international search report 18 May, 1999 (18. 05. 99)			
Name and mailing address of the ISA/ Japanese Patent Office		Authorized officer	
Facsimile No.		Telephone No.	

Form PCT/ISA/210 (second sheet) (July 1992)